

Original Article

## A Comparison of Non-Invasive Methods of Blood Pressure Measurement in Healthy Term Neonates

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### Abstract

**Background:** Invasive Blood Pressure (BP) monitoring in neonates is fraught with many complications and is rarely practical for routine monitoring, hence the need for alternative methods of BP measurements, especially in well neonates. This study aimed to compare BP measurements in neonates using Oscillometric and Doppler Ultrasound methods.

**Methodology:** One hundred and eighty-five neonates were consecutively recruited. Blood pressure measurements were taken at 12, 24, 36, and 48 hours of life using Doppler ultrasound with Aneroid Sphygmomanometer (DAM) (gold standard), Doppler ultrasound with Hybrid Sphygmomanometer (DHM), and oscillometric methods. Data was analysed using the IBM statistical package for the social sciences (SPSS) version 23. Comparison between the mean BP values obtained from different instruments was done using the paired Student t-test, and the degree of agreement between values was tested using the intra-class correlation coefficient scores. Bland-Altman analyses were also done. *P*-value was set at <0.05.

**Results:** Blood pressure increased gradually from 12 to 48 hours of life. The blood pressure values using the automated oscillometric method were significantly higher when compared to the values obtained using the gold standard ( $p < 0.001$ ), and the level of absolute agreement between the two methods was poor (intra-class coefficient < 0.5). Values from the DHM were not significantly different from those from the gold standard method ( $p > 0.05$ ), and the level of absolute agreement between the two methods was excellent (Intra-class correlation coefficient >0.9).

**Conclusion:** There was poor agreement between BP values using oscillometry when compared with DAM. However, the use of DAM or DHM demonstrated no difference in BP values. Caution should be exercised when interpreting values from oscillometric BP measurements in the newborn. On the other hand, either of the Doppler ultrasound methods may be used interchangeably.

**Keywords:** Blood pressure, neonates, Doppler ultrasound with anaeroid sphygmomanometer, Doppler ultrasound with hybrid sphygmomanometer, oscillometric device

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## Introduction

Blood pressure (BP) can be defined as the pressure generated because of blood flow through the arteries following the pumping action of the heart. [1] It is one of the essential vital sign parameters that is used in patient care and management, especially in conditions that may give rise to hypotension or hypertension with their attendant clinical consequences.

Blood pressure measurement in the neonate has its peculiarities, particularly because of certain factors such as the rapid haemodynamic changes seen in them, patient size, and fragility. [2] Thus, accurate measurement of blood pressure in this category of patients is imperative for the institution of prompt and adequate measures in cases of abnormality.

Blood pressure can be measured using both invasive and non-invasive methods. Invasive BP methods are the standard of care [3]; however, their use cannot be justified in otherwise well newborns because of the complications fraught with the procedure. These complications include local pain at the site of catheter insertion, paraesthesia, hematoma, bleeding, air embolism, vascular thrombosis and occlusion, vessel injury, pseudoaneurysm formation, and damping. [4] Hence, the a necessity of using suitable alternative methods of BP measurement, especially in resource-challenged environments such as ours. Non-invasive BP monitoring in neonates is generally done with oscillometric devices or Doppler ultrasound-aided measurements.

Oscillometric devices are the most widely used in BP measurement in neonates, and these devices measure the amplitude of pulsations within the blood vessel. However, owing to the variable algorithms used by different manufacturers for calibrating their instruments, this has led to a lack of comparability of BP values obtained by various devices. [5]

The use of Doppler ultrasound is another technique of non-invasive BP measurement that has been used in neonates, as it permits real-time, continuous BP monitoring, and it more readily detects the vessel wall pulsations in neonates in whom the fourth and fifth Korotkoff sounds may otherwise be difficult to hear or inaudible using conventional cuff-based devices. [3,6] Doppler-based measurements have been found to correlate better with values from intra-arterial BP monitoring in both children and adults [7] and thus may be considered a “non-invasive gold standard” for BP measurement in neonates, and have been applied as such in an earlier study [6]. Thus, this study aimed to measure BP in neonates using an oscillometric device and compare it to the Doppler ultrasound method, which served as the gold standard.

## Materials and methods

### *Study location*

This study was conducted in the postnatal ward of the University of Uyo Teaching Hospital, Uyo, a 750-bed tertiary healthcare facility, which is one of the main tertiary hospitals in Akwa Ibom state, south-south geopolitical zone of Nigeria.

### *Study design and study population*

The study was a cross-sectional analytical study involving healthy term (37-42 completed weeks GA) newborns aged 12-48 hours of life in the postnatal ward of the University of Uyo Teaching Hospital. On average, a total of 2,160 newborn babies are delivered per annum in the facility.

All newborns had a full clinical examination by the researcher before being enrolled in the study. Excluded newborns were those whose mothers were on any medications due to any comorbidities such as preeclampsia, human immunodeficiency virus, renal, respiratory, psychiatric, epilepsy, cancer diseases, hypertensive disorders of pregnancy, diabetes mellitus, or use of illicit substances during pregnancy. [8–11], those whose mothers had antepartum haemorrhage, chorionic villus sampling or amniocentesis, newborns with any identifiable congenital and physical deformity during examination, small for

gestational age newborns (less than 2.5kg or 2SD below mean for gestational age, macrosomic babies (babies weighing greater than 4kg), and newborns who were products of multiple gestation. All admitted infants, those with febrile illness or respiratory distress, were also excluded.

### *Ethical Considerations*

An ethical approval certificate was obtained from the Health Research Ethics Committee of the University of Uyo Teaching Hospital, Uyo, with certificate number UUTH/AD/S/96/VOL. XXI/575, and informed consent was obtained from either parent of each newborn to be studied after the objectives of the study had been clearly explained.

### *Sample Size Estimation*

The sample size determination was obtained using the formula [12] below;

$$n = \left( \frac{Z\sigma}{E} \right)^2$$

n = minimum sample size required

Z = the value from the standard normal distribution reflecting the confidence interval (CI), where 1.96 corresponds to a 95% CI.

$\sigma$  = the standard deviation of the outcome variable from a previous study, which is 12.9 [13].

E = the desired margin of error, which is 2

The minimum sample size is equal to

$$n = \left( \frac{1.96 (12.9)}{2} \right)^2$$

n = 159.82  $\cong$  160

Plus 20% attrition rate = 32

Sample size = 160 + 32 = 192

### *Study Protocol*

All consecutively born healthy term newborns who met the inclusion criteria were recruited into the study from the 12<sup>th</sup> hour of life at the postnatal ward after obtaining informed consent from either of the parents. Socio-demographic and clinical characteristics of the newborn and mother were obtained, and each baby had a proforma filled out.

The first BP measurement was taken 12 hours after birth and then at 12-hourly intervals until 48 hours of life. All babies had a total of four BP measurements. Blood pressure measurement of any newborn who was just fed was deferred and was carried out one hour post-feeding. The cuff size used for the study ensured that the mid-upper arm circumference corresponded to the arm circumference range on the cuff. The cuff was snugly applied on the right arm after palpating the brachial artery pulsation in the antecubital fossa and placing the artery mark on the cuff directly on the palpated arterial pulsation. The lower end of the cuff was about two centimetres above the antecubital fossa to allow easy access for the probe of the Doppler on the brachial artery. Thereafter, measurement was taken about fifteen minutes after the newborn had calmed down using a reusable cuff. In between the newborns, this reusable cuff was disinfected with the use of alcohol swabs. All the measurements were taken while the newborn was either awake but quiet or asleep. The BP measurement was recorded from the right arm while the neonate was in a supine position to exclude babies with coarctation of the aorta, which might give elevated BP values. The right arm was properly extended and positioned, and held down by the researcher.

The BP measurements were carried out using an automated oscillometric device, the Dinamap 8100<sup>®</sup>, and a handheld Doppler ultrasound (vascular Doppler VD-33<sup>®</sup>) simultaneously. The Dinamap 8100<sup>®</sup>, double

tube non-disposable cuff, and the sphygmomanometers [the desktop aneroid (Welch Allyn®) and hybrid (A &D medical UM-102®)] were connected to three separate Y connectors, respectively. These were connected to a 3-way clock. The desktop aneroid sphygmomanometer was positioned so that the pointer on the dial was at eye level with the lead researcher to avoid error due to parallax. Ultrasound conducting gel was applied to the skin overlying where the brachial pulse was palpated before placing the probe of the handheld Doppler ultrasound on the area at 45 degrees. While the devices were on, with the commencement of BP recording, the start button on the Dinamap 8100 was also switched on by an assistant. As the BP cuff was inflated and the probe was held in place below the cuff in the antecubital area, the Doppler signal was listened for while it diminished gradually till it disappeared on full inflation of the cuff, which signified the complete occlusion of the artery. With the onset of the deflation of the cuff, the point at which the sound reoccurred, and subsequent muffling signals were recorded using the desktop aneroid sphygmomanometer (which was noted by the researcher) and hybrid sphygmomanometer as the SBP and DBP values, respectively, for the handheld Doppler ultrasound, while the automated oscillometric device automatically gave SBP, DBP, and MAP values. The assistant, after pressing the start button on the automated oscillometric device, then placed his or her thumb on the mark button on the hybrid sphygmomanometer. The mark button was pressed on hearing the recurrence of the sound and at the onset of muffling signals of the Doppler ultrasound by the assistant. The SBP and DBP values obtained by an aneroid sphygmomanometer were read off by the researcher, while those of the hybrid sphygmomanometer at the point where the pressure bar display occurred were read off by the researcher and the assistant. The MAP of the handheld Doppler ultrasound with aneroid and hybrid sphygmomanometers was calculated using the formula  $[DBP + \frac{1}{3}(SBP-DBP)]$ .

The research team consisted of the lead researcher and 3 interns. A radiologist and a biomedical engineer trained the lead researcher on the use of the Doppler ultrasound and automated oscillometric device. The interns were trained on how to position the newborns for BP measurement and did the initial examination and anthropometric measurements. All BP measurements were taken by the lead researcher, assisted by the interns.

Three different readings were taken at an interval of 5 minutes by the two devices each time the BP measurement was carried out. The first was discarded, while the mean of the last two BP values recorded by each of the devices was calculated and recorded for further analysis. If the newborn cried during the process, the recording was discarded and commenced afresh, usually after the neonate quietened down (after about half an hour).

To ensure the accuracy of the instruments used, a biomedical engineer inspected and tested the instruments to ensure they were in good working condition prior to use. Also, a pilot study was carried out on twenty newborns in the University of Uyo Teaching Hospital (this was not included in the calculated sample size) before commencement of sample collection to test the efficacy of the research instruments. The batteries of the instrument were also fully charged and promptly replaced when necessary. The aneroid sphygmomanometer was calibrated twice during the course of sample collection when it was observed that the pointer deviated from the oval surrounding the zero-pressure gradation on the dial according to the manufacturer's instructions. Thereafter, the aneroid and a mercury sphygmomanometer were connected by a Y connector, and both were used to measure BP simultaneously to ascertain the accuracy of the aneroid sphygmomanometer. A senior neonatologist randomly rechecked the BP measurements at the pilot study phase and during the actual study in order to minimize errors and ensure that quality and confidence in test results were achieved.

### *Data Analysis*

Data was analysed using the International Business Machine Statistical Package for Social Sciences version 23. The normality of distribution of continuous variables was checked using the Kolmogorov-

Smirnov test. Normally distributed continuous variables were described using the mean and standard deviation. Skewed data were described using median and interquartile range or range. Categorical variables were described using frequency counts and percentages. The BP values using the various methods were summarized with the descriptive statistics of mean and standard deviation. Comparison between the different instruments was done using a paired t-test. The degree of agreement between the gold standard, Doppler with aneroid, and other instruments was assessed using the intra-class correlation coefficient scores  $<0.5$  = poor agreement,  $0.5$  to  $< 0.75$  = moderate agreement,  $0.75-0.90$  = good agreement,  $>0.90$  = excellent agreement. In addition, the assumption for the Bland Altman Graph was met, which was used to corroborate the findings of the intra-class correlation coefficient. Results were presented in prose, tables, and charts. All tests were two-tailed at 95% CI; p-value was considered significant if  $< 0.05$ .

## Results

One hundred and ninety-two newborns that met the inclusion criteria were consecutively recruited into the study. Seven (3.6 %) of 192 newborns recruited did not complete the study, as two developed fever at 24 and 36 hours of life, respectively, and were subsequently admitted into NICU, while the mothers of the other five newborns opted out. Hence, data of 185 (96.7 %) of the newborns who completed the study were included in the analysis. A total of 1,896 BP measurements were done using an automated oscillometric device and Doppler ultrasound with aneroid and hybrid sphygmomanometers simultaneously.

There were 93 females (50.3%) and 92 males (49.7%), giving a slight female preponderance with a female-to-male ratio of 1.01:1. The mean birth weight (SD) was 3.30kg ( $\pm 0.6$ ), and the mean birth length (SD) was 50.0cm ( $\pm 5$ ).

The time-specific blood pressure values using the automated oscillometric device are shown in Table 1. It shows that the mean blood pressure variables (systolic, diastolic, and mean arterial pressure) increased with age. The mean systolic blood pressure gradually increased from 63.51 mmHg at 12 hours to 74.28mmHg at 48 hours of life. This trend was similar for diastolic blood pressure and mean arterial blood pressure.

**Table 1:** Blood pressure values using the automated oscillometric device at specific times

Variables	Time (hours)	Mean $\pm$ SD	Range
Systolic Blood Pressure (mmHg)	12	63.51 $\pm$ 4.87	50.00 – 78.00
	24	66.82 $\pm$ 4.91	55.50 – 84.00
	36	70.67 $\pm$ 4.39	60.00 – 80.00
	48	74.28 $\pm$ 4.90	63.00 – 97.50
Diastolic Blood Pressure (mmHg)	12	36.18 $\pm$ 4.90	25.00 – 47.00

	24	38.29 ± 5.55	28.00 – 61.00
	36	39.60 ± 4.81	27.50 – 56.00
	48	41.86 ± 5.39	30.00 – 56.50
<b>Mean Arterial Pressure (mmHg)</b>	12	45.77 ± 5.87	32.00 – 61.00
	24	48.09 ± 6.39	33.50 – 69.00
	36	50.22 ± 5.88	30.50 – 68.00
	48	53.04 ± 6.49	35.50 – 74.00

SD = Standard Deviation, mmHg=millimeter mercury

The BP values using the Doppler method are shown in Table 2. The Doppler method was used with two different types of sphygmomanometers: the aneroid, which is the gold standard, and the hybrid. Doppler with both sphygmomanometers showed that the mean BP variables (SBP, DBP, and MAP) gradually increased with age. The MAP of Doppler with aneroid sphygmomanometer method gradually increased from 40.99 ± 2.25 at 12 hours to 45.07 ± 3.22 at 48 hours of life, while that of Doppler with the hybrid sphygmomanometer method gradually increased with age from 40.98 ± 2.25 at 12 hours to 45.06 ± 3.22 at 48 hours of life. This trend of increment was similar for SBP and DBP.

**Table 2:** Blood pressure values using the Doppler methods at specific times

Variables	Time (hours)	Mean ± SD	Range
<b>Doppler with an aneroid</b>			
Systolic Blood Pressure (mmHg)	12	57.36 ± 2.94	50.00 – 66.00
	24	58.83 ± 3.23	51.00 – 74.00
	36	61.08 ± 3.04	54.00 – 71.00
	48	63.41 ± 3.86	55.00 – 84.00
Diastolic Blood Pressure (mmHg)	12	32.81 ± 2.40	29.00 – 40.00
	24	33.75 ± 2.76	29.00 – 45.00
	36	34.68 ± 2.82	30.00 – 45.00
	48	35.93 ± 3.39	30.00 – 47.00
Mean Arterial Pressure (mmHg)	12	40.99 ± 2.25	31.67 – 47.33

	24	42.10 ± 2.51	36.33 – 52.67
	36	43.31 ± 2.47	37.33 – 52.67
	48	45.07 ± 3.22	35.67 – 58.00
<b>Doppler with a hybrid</b>			
Systolic Blood Pressure (mmHg)	12	57.36 ± 2.94	50.00 – 66.00
	24	58.87 ± 3.33	51.00 – 74.00
	36	61.03 ± 2.99	54.00 – 71.00
	48	63.38 ± 3.85	55.00 – 84.00
Diastolic Blood Pressure (mmHg)	12	32.80 ± 2.40	29.00 – 40.00
	24	33.75 ± 2.76	29.00 – 45.00
	36	34.68 ± 2.82	30.00 – 45.00
	48	35.93 ± 2.82	30.00 – 47.00
<b>Mean Arterial Pressure (mmHg)</b>	12	40.98 ± 2.25	31.67 – 47.33
	24	42.09 ± 2.52	36.33 – 52.67
	36	43.31 ± 2.47	37.33 – 52.67
	48	45.06 ± 3.22	35.67 – 58.00

SD = Standard Deviation, mmHg=millimetre mercury

Comparison of the blood pressure values between the automated oscillometric method and the gold standard, Doppler with aneroid sphygmomanometer method, is shown in Table 3. The table shows that across the intervals of measurement and various blood pressure variables (systolic, diastolic, and mean arterial pressure), the blood pressure values using the automated oscillometric method were significantly higher when compared to the values obtained using the Doppler with aneroid sphygmomanometer method ( $p < 0.001$ ). In addition, the level of absolute agreement when using the automated oscillometric method and Doppler with aneroid sphygmomanometer method across the intervals of measurement and the variables measured (systolic, diastolic, and mean arterial pressure) was poor (Intra-class correlation coefficient  $< 0.5$ ).

**Table 3:** Comparison of the blood pressure values at specified intervals between automated oscillometric and the Doppler with aneroid (gold standard) methods

BP values (mmHg)	Time (hours)	Mean (SD)	MD	t-test	p-value	Level of agreement using the Intra-class correlation coefficient (ICC)
SBP using AOM	12	63.51 (4.87)	6.15	20.88	<0.001	0.23
SBP using DAM		57.36 (2.94)				
SBP using AOM	24	66.82 (4.94)	7.99	32.83	<0.001	0.24
SBP using DAM		58.83 (3.27)				
SBP using	36	70.67 (4.40)	9.59	47.38	<0.001	0.17

<b>AOM</b>			61.08 (3.04)				
<b>SBP</b>	<b>using</b>						
<b>DAM</b>							
<b>SBP</b>	<b>using</b>	48	74.23 (4.90)	10.82	66.86	<0.001	0.22
<b>AOM</b>			63.41 (3.86)				
<b>SBP</b>	<b>using</b>						
<b>DAM</b>							
<b>DBP</b>	<b>using</b>	12	36.18 (4.90)	3.37	13.20	<0.001	0.43
<b>AOM</b>			32.81 (2.40)				
<b>DBP</b>	<b>using</b>						
<b>DAM</b>							
<b>DBP</b>	<b>using</b>	24	38.29 (5.56)	4.54	17.06	<0.001	0.43
<b>AOM</b>			33.75 (2.76)				
<b>DBP</b>	<b>using</b>						
<b>DAM</b>							
<b>DBP</b>	<b>using</b>	36	39.60 (4.81)	4.92	22.05	<0.001	0.39
<b>AOM</b>			34.68 (2.81)				
<b>DBP</b>	<b>using</b>						
<b>DAM</b>							
<b>DBP</b>	<b>using</b>	48	41.86 (5.39)	5.93	25.54	<0.001	0.40
<b>AOM</b>			35.93 (3.39)				
<b>DBP</b>	<b>using</b>						
<b>DAM</b>							
<b>MAP</b>	<b>usingAOM</b>	12	45.77 (5.87)	4.78	13.72	<0.001	0.27
<b>MAP</b>	<b>using</b>		40.99 (2.25)				
<b>DAM</b>							
<b>MAP</b>	<b>using</b>	24	48.02 (6.39)	5.92	16.34	<0.001	0.28
<b>AOM</b>			42.10 (2.51)				
<b>MAP</b>	<b>using</b>						
<b>DAM</b>							
<b>MAP</b>	<b>using</b>	36	50.22 (5.88)	6.91	20.23	<0.001	0.21
<b>AOM</b>			43.31 (2.47)				
<b>MAP</b>	<b>using</b>						
<b>DAM</b>							
<b>MAP</b>	<b>using</b>	48	53.04 (6.49)	7.97	22.89	<0.001	0.26
<b>AOM</b>			45.07 (3.22)				
<b>MAP</b>	<b>using</b>						
<b>DAM</b>							



SD = Standard Deviation, MD = Mean Difference, t = paired t-test, AOM = Automated oscillometric Method, DAM = Doppler with Aneroid Method, SBP=Systolic Blood Pressure, DBP = Diastolic Blood Pressure, MAP = Mean Arterial Pressure, BP = Blood Pressure, Intra-class correlation coefficients (Scores <0.5 = poor agreement, 0.5 to < 0.75 = moderate agreement, 0.75-0.90 = good agreement, >0.90 = excellent agreement), p < 0.05 indicates significance.

Comparison of the blood pressure values between the automated oscillometric method and the Doppler with the hybrid sphygmomanometer method is shown in Table 4. The table shows that across the intervals of measurement and various blood pressure variables (systolic, diastolic, and mean arterial pressure), the blood pressure values using the automated oscillometric method were significantly higher when compared to the values obtained using the Doppler with hybrid sphygmomanometer method (p < 0.001). Moreover, the level of absolute agreement between the automated oscillometric method and Doppler with the hybrid sphygmomanometer method across the intervals of measurement and the variables measured (i.e., systolic, diastolic, and mean arterial pressure) was also poor (Intra-class correlation coefficient < 0.5).

**Table 4: Comparison of the blood pressure values at specified intervals between automated oscillometric and Doppler with hybrid methods**

BP values (mmHg)	Time (hours)	Mean (SD)	MD	t-test	p-value	Level of agreement using the Intra-class correlation coefficient (ICC)
SBP using AOM	12	63.51 (4.87)	6.15	20.88	<0.001	0.23
SBP using DHM		57.36 (2.94)				
SBP using AOM	24	66.82 (4.94)	7.95	31.77	<0.001	0.24
SBP using DHM		58.87 (3.33)				
SBP using AOM	36	70.67 (4.40)	9.64	50.67	<0.001	0.18
SBP using DHM		61.03 (2.99)				
SBP using AOM	48	74.23 (4.90)	10.85	71.18	<0.001	0.22
SBP using DHM		63.38 (3.85)				
DBP using AOM	12	36.18 (4.90)	3.38	13.20	<0.001	0.43
DBP using DHM		32.80 (2.40)				
DBP using AOM	24	38.29 (5.56)	4.54	17.02	<0.001	0.42
DBP using DHM		33.75 (2.76)				

<b>DBP using DHM</b>						
<b>DBP using AOM</b>	36	39.60 (4.81)	4.92	22.05	<0.001	0.39
<b>DBP using DHM</b>		34.68 (2.81)				
<b>DBP using AOM</b>	48	41.86 (5.39)	7.18	25.54	<0.001	0.40
<b>DBP using DHM</b>		34.68 (2.82)				
<b>MAP using AOM</b>	12	45.77 (5.87)	4.79	13.77	<0.001	0.27
<b>MAP using DHM</b>		40.98 (2.25)				
<b>MAP using AOM</b>	24	48.02 (6.39)	5.93	16.34	<0.001	0.28
<b>MAP using DHM</b>		42.09 (2.52)				
<b>MAP using AOM</b>	36	50.22 (5.88)	6.91	20.23	<0.001	0.21
<b>MAP using DHM</b>		43.31 (2.47)				
<b>MAP using AOM</b>	48	53.04 (6.49)	7.98	22.90	<0.001	0.26
<b>MAP using DHM</b>		45.06 (3.22)				

SD = Standard Deviation, MD = Mean Difference, t = paired t-test, AOM = Automated Oscillometric Method, DHM = Doppler with Hybrid Method, SBP=Systolic Blood Pressure, DBP = Diastolic Blood Pressure, MAP = Mean Arterial Pressure, BP = Blood Pressure, Intra-class correlation coefficients (Scores <0.5 = poor agreement, 0.5 to < 0.75 = moderate agreement, 0.75-0.90 = good agreement, >0.90 = excellent agreement), p < 0.05 indicates significance.

Comparison of the blood pressure values between Doppler with the hybrid sphygmomanometer method and the gold standard, i.e., Doppler with aneroid sphygmomanometer method, is shown in Table 5. The table shows that across the intervals of measurement and various blood pressure variables (systolic, diastolic and mean arterial pressure), the blood pressure values obtained using the Doppler with the hybrid sphygmomanometer method were not significantly different in value from those obtained using the Doppler with aneroid sphygmomanometer method ( $p > 0.05$ ). In addition, the level of absolute agreement between Doppler with the hybrid sphygmomanometer method and Doppler with the aneroid sphygmomanometer method across the intervals of measurement and the variables measured (i.e., systolic, diastolic and mean arterial pressure) was excellent (Intra-class correlation coefficient >0.9).

**Table 5:** Comparison of the blood pressure values at specified intervals between the Doppler with hybrid and the Doppler with aneroid methods

<b>BP values (mmHg)</b>	<b>Time (hours)</b>	<b>Mean (SD)</b>	<b>MD</b>	<b>t-test</b>	<b>p-value</b>	<b>Level of agreement using Intra-class correlation coefficient (ICC)</b>
<b>SBP DHM using</b>	12	57.36 (2.94)	0.00	0.00	1.00	1.00
<b>SBP DAM using</b>		57.36 (2.94)				
<b>SBP DHM using</b>	24	58.87 (3.32)	0.04	0.76	0.45	0.97
<b>SBP DAM using</b>		58.83 (3.27)				
<b>SBP DHM using</b>	36	61.02 (2.99)	-0.06	-1.00	0.32	0.97
<b>SBP DAM using</b>		61.08 (3.04)				
<b>SBP DHM using</b>	48	63.37 (3.85)	-0.04	-0.43	0.67	0.98
<b>SBP DAM using</b>		63.41 (3.86)				
<b>DBP DHM using</b>	12	32.80 (2.40)	-0.01	-1.00	0.32	1.00
<b>DBP DAM using</b>		32.81 (2.40)				
<b>DBP DHM using</b>	24	33.75 (2.76)	0.00	0.00	1.00	1.00
<b>DBP DAM using</b>		33.75 (2.76)				
<b>DBP DHM using</b>	36	34.68 (2.82)	0.00	0.00	1.00	1.00
<b>DBP DAM using</b>		34.68 (2.81)				
<b>DBP DHM using</b>	48	40.98 (2.25)	5.05	0.00	1.00	1.00
<b>DBP DAM using</b>		35.93 (3.39)				
<b>MAP DHM using</b>	12	40.97 (2.25)	-0.02	-1.62	0.11	1.00

<b>MAP DAM</b>	<b>using</b>		40.99 (2.25)				
<b>MAP DHM</b>	<b>using</b>	24	42.09 (2.52)	-0.01	-0.09	0.93	0.91
<b>MAP DAM</b>	<b>using</b>		42.10 (2.51)				
<b>MAP DHM</b>	<b>using</b>	36	43.31 (2.47)	0.00	-1.35	0.18	1.00
<b>MAP DAM</b>	<b>using</b>		43.31 (2.47)				
<b>MAP DHM</b>	<b>using</b>	48	45.04 (3.22)	-0.03	-1.39	0.17	1.00
<b>MAP DAM</b>	<b>using</b>		45.07 (3.22)				

SD = Standard Deviation, MD = Mean Difference, *t* = paired *t*-test, DAM = Doppler with Aneroid Method, DHM = Doppler with Hybrid Method, SBP=Systolic Blood Pressure, DBP = Diastolic Blood Pressure, MAP = Mean Arterial Pressure, BP = Blood Pressure, Intra-class correlation coefficients (Scores <0.5 = poor agreement, 0.5 to < 0.75 = moderate agreement, 0.75-0.90 = good agreement, >0.90 = excellent agreement), *p* < 0.05 indicates significance.

The systematic assessment of the differences in BP values using the Bland-Altman analyses is shown in Figures 1 to 3. The Bland Altman graphs show agreement between SBP, DBP and MAP difference and mean using Aneroid and Hybrid sphygmomanometers, with the differences of the values falling within 95% CI of the graph.

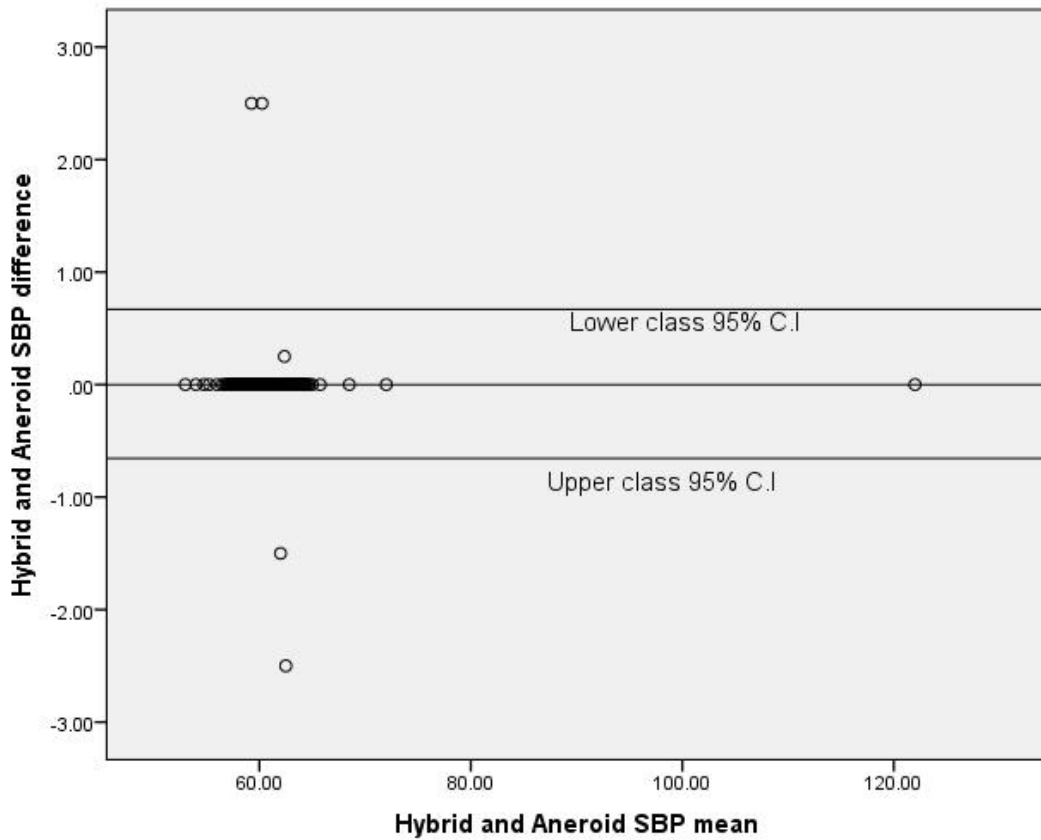


Figure 1: Bland Altman graph showing agreement between the SBP values of Doppler with the Hybrid and Aneroid method

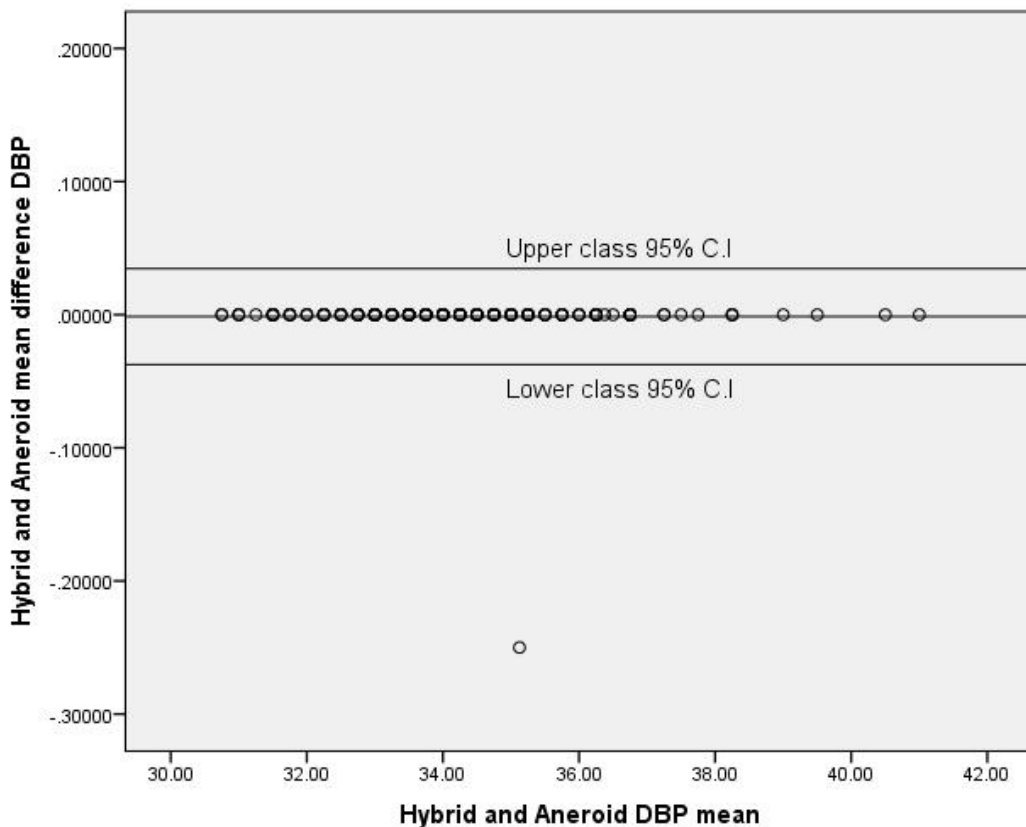


Figure 2: Bland Altman graph showing agreement between the DBP values of Doppler with Hybrid and Aneroid methods

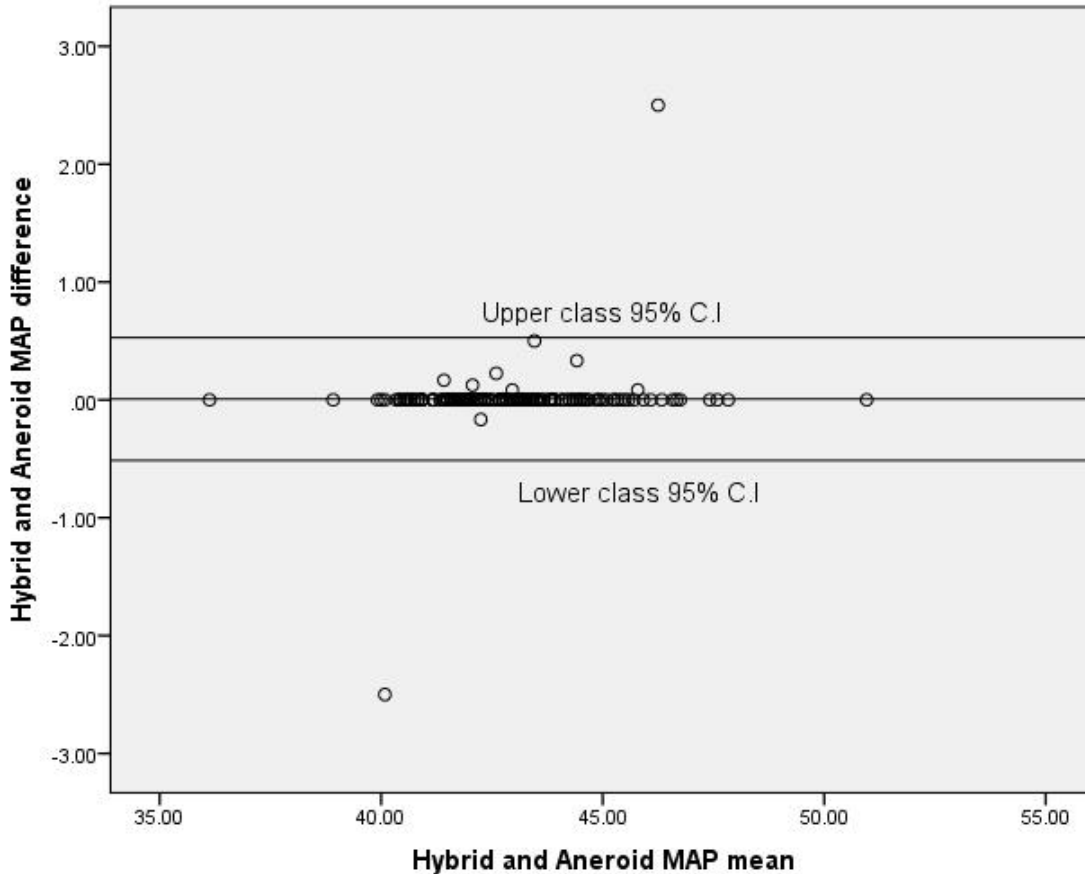


Figure 3: Bland Altman graph showing agreement between MAP values of Doppler with Hybrid and Aneroid methods

## Discussion

Blood pressure is one of the vital sign parameters that is essential in the clinical management of newborns, thus making the use and availability of appropriate measurement instruments imperative. The paucity of studies on BP values in neonates and, in particular, the lack of comparative studies on non-invasive methods of BP measurement in our environment make the findings of this study indispensable.

In the index study, BP values obtained using the automated oscillometric method were comparable with other studies done in neonates in the country over a ten-year period. [14–16] All the highlighted studies demonstrated progressive increase in BP values with increasing age of the study subjects, with higher BP values obtained using AOM when compared to Doppler method as also noted in this study and by Nascimento et al. [13] This noted similarity in BP values and trend may be adduced to the fact that these measurements were carried out in apparently healthy term newborns that had normal transition from intrauterine to extrauterine life. Also, other factors that might have been responsible for the similarity in BP values obtained using the AOM were the use of the same type of Oscillometric device in two of the quoted studies [14,15], which was the same device used in this index study, thus making the values obtained comparable because of the same clinical algorithms used in the devices. In addition, the

accommodation effect was taken into cognizance both in the index study and in those quoted above in which the average of three BP values per reading was taken.

However, the findings in this study contrasted with those by Nascimento et al [13], who obtained much higher BP values at the 24<sup>th</sup> hour of life using both oscillometric (SBP  $83.2 \pm 12.4$ , DBP  $60.2 \pm 11.3$ , MAP  $46.2 \pm 9.8$ mmHg) and Doppler methods (SBP  $79.8 \pm 12.6$ mmHg). This observed difference may be due to the inclusion of newborns whose mothers were hypertensive, with maternal hypertension being a factor that has been implicated in elevated blood pressure in newborns. [17,18] The increase in BP values with increasing post-natal age may be due to a rise in systemic vascular resistance when the cord is clamped, associated with the subsequent fall in pulmonary vascular resistance following lung expansion.

As earlier noted, there are no known comparable studies done in our environment that used Doppler with an aneroid sphygmomanometer; however, Nascimento *et al* [13] combined Doppler with a mercury sphygmomanometer and obtained higher BP values between the 12<sup>th</sup> hour and 24<sup>th</sup> hour of life compared to the index study. This may be because of the earlier noted inclusion of babies of hypertensive mothers. In addition, the trend of increasing BP values with age measured with Doppler methods was also similar to findings in this study, in which Doppler with aneroid and Doppler with hybrid sphygmomanometers were used.

The outcome of the comparison between the automated oscillometric device method with either of the Doppler methods in this index study gave persistently higher blood pressure values, which were statistically significant and demonstrated a poor level of agreement across all the BP parameters. Dionne et al in their meta-analyses also corroborated these higher BP values within the first five days of life obtained by use of automated oscillometric devices, howbeit compared to the intra-arterial (invasive) method of BP measurement. [3]

Direct comparison of these methods of BP measurement is difficult as there is no known available study that directly compared the level of agreement between the automated oscillometric method with Doppler ultrasound methods, either using aneroid or hybrid sphygmomanometers in the newborn. However, Nascimento *et al* [13] in their comparative study using the automated oscillometric device method with Doppler with mercury sphygmomanometer found a strong positive correlation between the two methods, although correlation is not synonymous with level of agreement.

There was excellent agreement (by Bland Altman analyses) between the methods of BP measurement using Doppler with aneroid sphygmomanometer versus Doppler with hybrid sphygmomanometer in this study, with no significant difference between the blood pressure values obtained using these devices: thus, these two methods can be used interchangeably. As previously noted, only the study by Nascimento et al [13] used Doppler with a mercury sphygmomanometer, contrary to the index study, which used aneroid and hybrid sphygmomanometers, thereby making comparison between the two studies untenable.

A major limitation of this study was the inability to perform intra-arterial BP measurements, which remains the gold standard for measurement of BP in neonates because of the degree of invasiveness, which is not justifiable in well neonates. [10] Thus, blood pressure measurement with Doppler using an aneroid sphygmomanometer was used as the reference standard in this study because of the phasing out of mercury sphygmomanometers in clinical practice.

## Conclusion

In conclusion, blood pressure values of well neonates in this study showed a gradual increase over the first 48 hours of life, regardless of the method of blood pressure measurement used. However, values obtained using an automated oscillometric device were significantly higher and showed poor agreement with Doppler methods, while, on the other hand, the use of Doppler methods with either aneroid or hybrid sphygmomanometers demonstrated no significant difference in BP values. Thus, both Doppler methods may be used interchangeably.



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